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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,003	11/07/2001	Shiguang Yu	6601-00	5003

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/683,003	YU ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/26/2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of poor hair growth or alopecia, does not reasonably provide enablement for prevention of poor hair growth or alopecia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The claims are directed to prevention or treatment of poor hair growth or alopecia with about 0.1 to about 4.5 mg/Kg of selenium.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record provides evidence of treatment but not prevention of poor hair growth or alopecia. As such, it appears that prevention is of low predictability.

The amount of direction or guidance present and the presence or absence of working examples:

Applicant provides only an example in which hair is directly removed, as such, there is no showing of prevention of poor hair growth or alopecia.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim prevention, however, Applicant has not shown that administration of selenium does prevent poor hair growth or alopecia. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine whether prevention occurred.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Applicant provides no evidence which shows that administration of selenium will prevent poor hair growth or alopecia.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald (Abstract).

McDonald discloses that oral administration of 0.1 mg/kg of selenium to lambs resulted in fleece weight which was 14.4% higher and wool production which was 39% higher than surviving untreated lambs (Abstract).

Examiner has duly considered Applicant's arguments but deems them unpersuasive. The limitation "about" includes amount below 0.5 mg/kg. Applicant has not defined the limitation "about", as such, Applicant has not shown that about 0.5 mg/kg excludes 0.1 mg/kg of selenium.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/11122, Lee et al., Shield, Jr. et al., Hayek et al., Arthur et al., Ahsan et al. and Messenger.

WO 98/11122 disclose that low levels of selenium have be associated with hair abnormalities (pg. 2, lines 9-14). It is disclosed that the nutritional supplement contains a dosage of about 10 micrograms to about 5 mg (Pg. 10, lines 16,17). It is disclosed that the nutritional supplement has application in the veterinary fields (Abstract).

Lee et al. (Aust. J. Agric. Res. (1999)) disclose that recommended dietary selenium requirement in the US for sheep is 0.1-0.3 mg/kg and that the critical concentration of Se in blood necessary to support wool growth is 900 nmol Se/L for breeding ewes and 500 or 800 nmol Se/L for non-breeding sheep Pgs. 1344,1345).

Shields, Jr. et al. disclose a composition which is fed to dogs containing a minimum of 0.4 mg/kg or selenium (Example 4, Column 19, lines 63-68, Column 20)

Hayek et al. disclose a composition which is fed to dogs containing 0.27 mg/kg of selenium (Table 8, Column 18, lines 44-68, Column 19, lines 1-18).

Arthur et al. disclose that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases which convert thryroxine to the more metabolically active triodothyronine (T3) (Abstract).

Ahsan et al. disclose that triodothyronine stimulates the proliferation and/or metabolism of outer root sheath cells and dermal papilla cells (Abstract).

Messenger discloses that thyroxine, which is converted to the active hormone triodothyronine, increased hair length in rats and hair growth in sheep and badgers (pg. 633).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for controlling the rate of hair growth or treating poor hair growth or alopecia in a dog or cat with about 0.1 to about 4.5 selenium mg/kg. However, the prior art amply suggests the same as it is disclosed that selenium is critical to wool production, that selenium is given as a nutrient supplement in animals, including dogs and that selenium deficiency results in T3 deficiency, that T3 stimulates hair cell growth and/or metabolism and that administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in sheep and badgers. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to administer similar amounts of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

"Any judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include

knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 170 USPQ 209, 212 (CCPA 1971). Further, contrary to Applicant's arguments, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 69 USPQ2d 1686, 1690 (Fed. Cir. 2004).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

The amount disclose in Lee et al. is a recommended daily amount. Lee et al. does not exclude the use of greater amounts and Applicant has not shown that the term "about" excludes the recommended amounts.

There is no requirement that Shield et al. or Hayek et al. indicate that the amounts are suitable for treatment of alopecia or poor hair growth. The reference are merely cited to provide disclosure of nutritional supplements for dogs which contain selenium which in view of the other references would motive one of ordinary skill in the art to expect that the same would be effective in increasing hair growth.

The three remaining three references disclose the mechanism by which administration of selenium can effect increase hair growth. Applicant is correct that by themselves they do not

disclose or suggest every limitation in claims 2 or 3. However, there is no requirement that they do so. The rejection herein is based on the combination of all references which motivation to combine, Examiner has indicated above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
December 12, 2005

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
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